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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,735	04/04/2001	Jian-Kang Zhu	205645US20	9738

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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/20/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,735

Applicant(s)

ZHU ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 and 36-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. The amendment filed 2/21/2003 has been entered.

Claims 1-42 are pending.

Claims 23-31, and 36-42 are withdrawn from consideration for being drawn to non-elected inventions.

Claims 4-8 and 33-35 have been amended.

2. Claims 1-22, and 32-35 are examined in the present office action.

3. This application contains claims 23-31 and 36-42 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims (37 CFR 1.144) See MPEP § 821.01.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or

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other form of browser-executable code. See for example, page 12, lines 21 and 22. See MPEP § 608.01.

Utility

7. Claims 1-22 and 32-35 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/21/2002.

Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

Applicants contend that the present application is in full compliance with 35 U.S.C. §101 because Applicant's invention fulfills at least one credible assertion test for utility. Applicants list as utility, a nucleotide sequence for the *sos2* gene, amino acid sequence for the SOS2 protein, method of making the SOS2 protein, method of making a transgenic plant, method of screening for polynucleotides which encode a protein having serine/threonine kinase activity and lastly, method of increasing the salt tolerance in a plant. Applicants believe that the Examiner has not presented a prima facie showing of lack of utility. Applicants contend that it is not a requisite of the Applicant to understand the mechanism of action of Applicant's invention. Applicants believe they have provided an extensive explanation of the problem to be solved by describing the sodium and potassium relationships that are caused during salt stress and the "role played by the present inventive polynucleotides and proteins, which once again satisfies the 'need only make one credible assertion' test set forth by the CCPA in Gaubert" (page 12, 1st full paragraph).

The Examiner asserts that Applicant's invention lacks a credible utility, even with Applicant's assertion that only one utility satisfies the utility requirement. Applicant is claiming

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a polynucleotide of SEQ ID NO:1 encoding SEQ ID NO:2, including sequences exhibiting varying degrees of sequence identity (i.e., 70% to 90% sequence identity), methods of making a transgenic plant and method of increasing the salt tolerance of a plant comprising the claimed polynucleotide. Applicants have disclosed that their invention is a serine/threonine protein kinase. The prior art teaches the involvement of protein kinases in a wide array of biological process, except in relation to salt tolerance. The prior art does not teach how one skilled in the art could use a serine/threonine protein kinase to enhance salt tolerance. Given the lack of teaching in the prior art in regards to how one skilled in the art uses protein kinases to enhance salt tolerance, it becomes necessary for Applicant to teach by way of disclosure or example, how one skilled in the art can use a protein kinase to enhance salt tolerance. Applicants have not shown that a plant transformed with SEQ ID NO:1 would exhibit a phenotype any different than a plant not transformed with said polynucleotide. Applicants have explained the importance of maintaining the proper sodium to potassium ratios but Applicants have not transformed a plant with their invention so as to see if in fact the claimed sequence produces a protein that affects a plant's tolerance to a salt environment. It is true, that Applicant does not have to understand the mechanism by which their invention operates, but absent any evidence from either the prior art or from Applicant that serine/threonine protein kinases are involved in salt tolerance, the Office maintains its *prima facie* utility rejection as set forth in the office action mailed 11/21/2002.

Written Description

8. Claims 5-8, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/21/2002. Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

Applicants believe that this ground of rejection is based on the absence of a description of domains that are specific to this particular serine/threonine kinase or domains that are important for its proper function (page 12, last paragraph). Applicants have amended claims 5-8 to include a recitation that the isolated polynucleotides within the scope of these claims encode a protein having serine/threonine kinase activity.

Applicants understanding of the problem is partially correct, but adding a recitation that the isolated polynucleotides encode a protein having serine/threonine kinase activity does not fulfill the written description requirement. There are hundreds of serine/threonine kinases. Applicant has not disclosed a representative number of serine/threonine kinases having 70% identity with SEQ ID NO:1. Based on the disclosure of SEQ ID NO:1, one skilled in the art would not be able to predict the structure of other serine/threonine kinases having 70% sequence identity. Applicant has not provided either a description of the domains characteristic to Applicant's invention nor has Applicant provided an assay that evaluates if a particular serine/threonine kinase functions or has the same activity as SEQ ID NO:2.

Enablement

9. Claims 1-22 and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 11/21/2002. Applicant's arguments filed 2/21/2003 have been fully considered but they are not persuasive.

Applicants contend that with respect to claims 1-4, 9-22 and 32-33, the Examiner has not provided any reason and/or explanation for rejecting these claims as lacking enablement.

The Examiner would like to draw Applicant's attention to page 10, 2nd paragraph to page 13, 2nd paragraph of the office action mailed 11/21/2002 for the reasons Applicant's inventions is not enabled.

Applicants contend that the rejection of claims 5-8, in particular, those claims drawn to sequences exhibiting 70% to 90% sequence identity with SEQ ID NO:1 or sequences that hybridize to SEQ ID NO:1; Applicants believe that this rejection is obviated by the amendment present herein. Now claims 5-8 recited polynucleotides that encode proteins having serine/threonine kinase activity. Applicants contend that the specification teaches one skilled in the art how to isolated, express and characterize any sequence variant to assess its standing with respect to the claimed invention. In addition, the amended claims now recite an activity which provides sufficient direction for the skilled artisan to determine if a sequence is encompassed in the claimed invention (page 14, 2nd paragraph).

The disclosure on page 12, line 18 to page 16, line 26 taken with the amended claims which recite sequences having serine/threonine kinase activity do not provide the added information which fulfills the enablement requirement. The disclose in the specification as cited above, only provides guidance for one skilled in the art to isolate the same nucleic acid of SEQ

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ID NO:1 encoding SEQ ID NO:2 from *Arabidopsis*. The disclosure does not teach which regions of the protein are essential and required for the protein's proper activity as a protein kinase and as a protein kinase involved in salt tolerance. It is true that the claims now recite a serine/threonine kinase activity, but there are many serine/threonine protein kinases. Applicant has not taught what other domains or regions are important for their invention. In addition, Applicant has only taught how to assess a protein for kinase activity, but has not provided an assay specific to the polypeptide encoded of SEQ ID NO:2. Applicant has not taught the domains that are necessary for salt tolerance, for Applicant's particular protein kinase.

In regards to claims 34-35, Applicant contends that the Examiners discourse surrounding the interaction of SOS2 with SOS3 is a misapplication of the test for enablement. In addition, Applicants provide a detailed example on page 16, lines 10-26 of how to assess the up-regulation of expression due to salt stress. Applicants contend that the allegation that "just because the *sos2* mutants exhibit an increased sensitivity to high sodium concentrations, does not mean that over-expressing SOS2 will automatically produce plants with an increased tolerance to sodium" is of no moment (page 16, 1st paragraph). Applicants submit, that one skilled in the art could assess increased salt tolerance based on SOS2 expression as described in the specification.

Applicant's traversals have been carefully considered and are found unpersuasive for the following reasons. Just because one skilled in the art can assess if SOS2 is upregulated in the roots of a plant does not provide enablement for claims drawn to a method of increasing salt tolerance in a plant comprising overexpressing SOS2 in a plant. Applicants discovered that SOS2 is present in roots and shoots at low levels and that in plants exposed to a salt treatment, the expression of SOS2 mRNA increased compared to plants that were not treated with salt.

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This experiment only shows that SOS2 mRNA is increased during salt treatment and does not address whether overexpression of SOS2 will make plants tolerant of increased salt in their environment.

10. In regards to the IDS filed 8/17/2001, which lists pending application numbers 09/824,734 and 09/824,735 therein, the before applications have been noted.

11. No claims are allowed. SEQ ID NO:1 and 2 are free of the prior art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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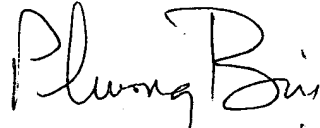
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

May 16, 2003


PHUONG T. BUI
PRIMARY EXAMINER 5/19/03